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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/216,062	12/18/1998	YAJUN GUO	239/102	1297

7590 03/26/2004

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EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/216,062	Applicant(s) GUO, YAJUN	
	Examiner DiBrino Marianne	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-49, 53-56, 58-62, 65-77, 81-84, 86-95 and 98-110 is/are pending in the application.
- 4a) Of the above claim(s) 54, 55, 65, 67, 68, 76, 75-77, 82, 83, 98, 100 and 101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-49, 53, 56, 58-62, 66, 69-74, 81, 84, 86-95, 99 and 102-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/03 has been entered.
2. Applicant's amendment filed 11/28/03 is acknowledged and has been entered.
3. Applicant is reminded of Applicant's election of the species of hepatocellular carcinoma cells, bispecific antibody for 4-1BB/gp95 and TNF-alpha and IFN-gamma treated cells and TNF-alpha and IFN-gamma in Paper No. 26. Because the Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Claims 45-49, 53, 56, 58-62, 66, 69-74, 79, 81, 84, 86-95, 99 and 102-110 read on the elected species enunciated above.

Accordingly, claims 54, 55, 65, 67, 68, 75-77, 82, 83, 98, 100 and 101 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 45-49, 53, 56, 58-62, 66, 69-74, 81, 84, 86-95, 99 and 102-110 are currently being examined.

4. The disclosure is objected to because of the following informalities:

Applicant is required to amend the specification (i.e., the paragraph spanning pages 24 and 25) to disclose the name and address of the depository for the cell lines disclosed in the specification.

Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 45-49, 53, 56, 58-62, 66, 69-74, 81, 84, 86-95, 99 and 102-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a. The specification does not disclose how to make and/or use the instant invention. The claimed method of making a composition and the said composition comprises the making and or/use of hepa 1-6 cells, recited in instant claims 62 and 95. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass a composition which comprises a cell line designated "hepa 1-6". The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed compositions can be made and/or used.

The instant specification discloses working examples for (on pages 41-42 and 44-45) use of the invention (irradiated tumor cells armed with gp115xCD28 bispecific mAb) to cause hepa 1-6 hepatoma tumor cell regression in mice and to cause tumor regression of SMCC-1 colon carcinoma in mice, respectively. The specification further discloses on page 23 at lines 10-11 that "Hepa 1-6 is a chemically induced hepatoma originating in a C57BL/6 mouse (G. J. Darlington et al., 1980, J. Natl. Cancer Inst. 64: 809)."

The specification does not appear to disclose whether the said Hepa 1-6 hepatoma cells are readily available to the public, nor does the specification disclose a repeatable method for obtaining the said cells. It is apparent that the said cells are required to practice the claimed invention. As a required element, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If the said cells are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the relevant cell lines. See 37 CFR 1.802.

There is insufficient guidance in the specification as to how to make and/or use the instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

b. The specification does not disclose how to make and/or use the instant invention. The claimed method of making a composition and the said composition comprises the making and or/use of compositions comprising hepatocellular carcinoma cells, lymphoma cells, colon carcinoma cells or gastric cancer cells. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass the making and/or use of compositions comprising non-irradiated cancer cells.

The specification discloses that the composition of the instant invention is useful in treating cancer (especially page 21 at lines 8-19).

Evidentiary reference U.S. Patent No. 5,484,596 discloses using irradiated tumor cells as a vaccine in order that the injected tumor cells do not proliferate when administered in vivo (especially Abstract).

There is insufficient guidance in the specification as to how to make and/or use the instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

c. The specification does not disclose how to make and/or use the instant invention. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claims encompass a method of preparing a therapeutic vaccine composition. The state of the art is such that it is unpredictable in the absence of appropriate evidence whether the claimed compositions can be made and/or used.

The instant specification discloses working examples for (on pages 41-42 and 44-45) use of the invention (irradiated tumor cells armed with gp115xCD28 bispecific mAb) to cause hepa 1-6 hepatoma tumor cell regression in mice and to cause tumor regression of SMCC-1 colon carcinoma in mice, respectively. The specification further discloses on page 23 at lines 10-11 that "Hepa 1-6 is a chemically induced hepatoma originating in a C57BL/6 mouse (G. J. Darlington et al., 1980, J. Natl. Cancer Inst. 64: 809)." The specification further discloses (in Example 16) human clinical data on human hepatocellular carcinoma and colon cancer using CD28:gp115 bispecific Mab armed cancer cells, i.e., administration of the cellular compositions of the invention in vivo in patients in stages II-IV in HCC and in patients with colon cancer who had distant metastasis.

The specification does not disclose making a therapeutic vaccine composition useful for prevention of cancer.

Evidentiary reference Encyclopedia Britannica Online (2004) defines vaccine as "suspension of weakened, killed, or fragmented microorganisms or toxins or of antibodies or lymphocytes that is administered primarily to prevent disease."

There is insufficient guidance in the specification as to how to make and/or use the instant invention. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 62 and 95 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62 and 95 are indefinite in the recitation of "hepa 1-6" cells because the characteristics of the said cells are not known. The use of "hepa 1-6" as the sole means of identifying the cells renders the claim indefinite because "hepa 1-6" is merely a laboratory designation which does not clearly defined the claimed product.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 70-74, 81, 84, 86-95, 99 and 102-110 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 103, 107, 110-115, 118, 119, 121-124, 126-137, 140-142, 144 and 145 of copending Application No. 08/872,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the 08/872,527 application are encompassed by the instant claims.

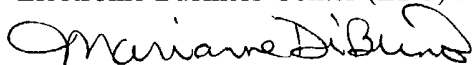
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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